

March 6, 1989, is codified as part of the authorized hazardous waste management program under Subtitle C of RCRA, 42 U.S.C. 6921 *et seq.*

(c) Statement of Legal Authority. (1) "Attorney General's Statement for Final Authorization," signed by the Attorney General of Ohio on July 1, 1985, is codified as part of the authorized hazardous waste management program under Subtitle C of RCRA, 42 U.S.C. 6921 *et seq.*

(2) Supplemental "Attorney General's Statements for Final Authorization," and addenda to such Statements signed by the Attorney General of Ohio on December 30, 1988, and February 24, 1989, are codified as part of the authorized hazardous waste management program under Subtitle C of RCRA, 42 U.S.C. 6921 *et seq.*

(d) Program Description. The Program Description and any other materials submitted as part of the original application or as supplements thereto are codified as part of the authorized hazardous waste management program under Subtitle of RCRA, 42 U.S.C. 6921 *et seq.*

§§ 272.1802 through 272.1849 [Reserved]
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40 CFR Parts 710 and 720

[OPTS-50039; FRL-3609-1]

Polymers Manufactured Using Free-Radical Initiators; Clarification of Reporting Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Clarification of rule.

SUMMARY: Under section 5 of the Toxic Substances Control Act (TSCA), any person who intends to manufacture or import a new chemical substance for non-exempt commercial purposes must notify EPA at least 90 days before manufacture or import begins. In this document, EPA is clarifying the section 5 premanufacture notification (PMN) requirements and section 8(b) Inventory reporting regulations for polymers manufactured using one or more free-radical initiators. To ensure that new chemical substances are properly reviewed before they are manufactured, EPA has concluded that free-radical initiators used at greater than two weight percent in the manufacture of a polymer must be included in the description of a polymer for the TSCA Inventory and for PMN purposes. However, EPA has decided to apply this policy only to polymers not listed on the

Inventory as of the effective date of this document.

DATE: This document is effective July 28, 1989.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: This document clarifies the PMN requirements and Inventory reporting regulations for polymers manufactured using one or more free-radical initiators.

I. Background

Several polymer manufacturers have raised the issue of whether or not free-radical initiators used in the manufacture of a polymer are required to be included in the TSCA section 8(b) Inventory description of the polymer. In particular, one polymer manufacturer asked if EPA had changed its policy regarding the description of polymers on the Inventory based on the Inventory Reporting Regulations (40 CFR Part 710) published in the *Federal Register* of December 23, 1977 (42 FR 64572), and the final PMN rule (40 CFR Part 720) and subsequent clarifications published in the *Federal Register* of May 13, 1983 (48 FR 21722), and September 13, 1983 (48 FR 41132), respectively. EPA's policy on polymers has not changed. However, EPA has become increasingly aware of the confusion surrounding this issue and polymer manufacturers' concerns regarding compliance with the PMN requirements in this area. Therefore, EPA has carefully reviewed its prior policy statements regarding the Inventory and PMN descriptions of polymers, including polymers manufactured using free-radical initiators.

In the Inventory Reporting Regulations (40 CFR Part 710), EPA required the reporting of polymers in terms of constituent monomers used at greater than two weight percent. Section 710.5(c) set out the reporting requirements:

Reporting polymers. (1) To report a polymer a person must list in the description of the polymer composition at least those monomers used at greater than two percent (by weight) in the manufacture of the polymer.

(2) Those monomers used at two percent (by weight) or less in the manufacture of the polymer may be included as part of the description of the polymer composition.

Note.—The "percent (by weight)" of a monomer is the weight of the monomer expressed as a percentage of the weight of

the polymeric chemical substance manufactured.

The Inventory Rule did not define "monomer." However, also in December 1977, EPA published an instruction booklet, "Reporting for the Chemical Substance Inventory," which amplified the rule as follows:

The polymer description should identify only monomers and other reactive ingredients such as chain-transfer or cross-linking substances. Other additives, such as emulsifiers and plasticizers, which are not chemically a part of the polymeric composition should not be identified in the description of the polymer, and their weight should not be included in estimating the 'dry' weight of the polymer.

The phrase "monomers and other reactive ingredients" identifies reactivity as the feature required for an ingredient to be a part of the polymer composition. Thus chain-transfer agents, often thought of as merely controlling the molecular weight of the polymer without adding any properties of their own, are explicitly identified as reportable.

For the most part, the May 13, 1983 PMN rule (40 CFR Part 720) adopted the information requirements of the Inventory Reporting Regulations and of the October 1979 proposed PMN rule. However, the reporting requirements for polymers (40 CFR 720.45(a)(3)) were modified slightly. They read as follows:

For polymers, the notice must identify monomers and other reactants used in the manufacture of the polymer by chemical name and CAS Registry number (if available). The notice must indicate the typical percent of each monomer and other reactant in the polymer (by weight percent of total polymer); the maximum residual of each monomer present in the polymer; and a partial or incomplete structural diagram, if possible. The notice must provide estimates of the minimum number-average molecular weight of the polymer and the amount of low weight species below 500 and below 1,000 molecular weight and describe how the estimates were obtained.

In the PMN rule, monomers and other reactants were not distinguished. Although the phrase "maximum residual" was applied only to monomers, explanatory language (48 FR 21732) stated that: "[i]nstead of providing the range of composition of each monomer in the polymer, manufacturers need only estimate the typical composition of the monomers and other reactants, e.g., catalysts and initiators."

The purpose of the change from the October 1979 proposal was only to replace "range of composition" with "typical composition." Unfortunately, the juxtaposition of the terms

"catalysts" and "initiators" seems to have led to a misunderstanding. Free-radical initiators have often been loosely referred to in industrial parlance as "catalysts," because like catalysts they increase the rate of reactions. However, unlike true catalysts, they are not regenerated at the end of a cycle of the reaction sequence, but are consumed by the reactions they initiate. The explanatory language in the preamble of the PMN rule could be read to suggest that *both* initiators *and* catalysts should be included in the composition of the final polymer.

The September 13, 1983 (48 FR 41134), clarification stated that: "all monomers and other reactants used at greater than two percent are automatically included in the polymer name on the Inventory." There is also specific reference to initiators in the statement: "Reactants other than monomers include cross-linking agents, chain-terminating agents, free-radical initiators, and any other reactant which is intended to be incorporated into the structure of the polymer."

In response to comments on the October 1979 proposal and the May 1983 final rule, EPA indicated in the September 13, 1983 clarification that catalysts as such need not be included in the composition of a polymer:

* * * [S]ubstances should be listed in Part I(B)(2)(b) of the form only if they are intended to become incorporated into the polymer structure. If the manufacturer does not intend for the starting material to be incorporated into the polymer, it does not have to be listed in this section. For example, a starting material should not be listed in this section if it serves only to influence polymer formation without becoming a part of the new chemical substance, or if it is not intended to become part of the substance but is inadvertently incorporated into the polymer's structure. These materials, however, must be identified in other sections of the form.

Agents such as nonreactive surfactants, solvents, and catalysts and cocatalysts may be used during the manufacture of the polymer. If these agents are not intended to become chemically a part of the polymer, but if they remain in the polymer as impurities, they should be listed in Part I(B)(3) under impurities* * *. These agents must also be identified, whether or not they may occur as polymer impurities, in the Process Description (Part I(A)(1)) * * *.

EPA's clarification cannot be construed to extend the exemption of catalysts to the case of initiators. No general property of a catalyst requires it to become chemically incorporated in the polymer whose polymerization it is catalyzing (although such incorporation may in some cases occur). In contrast, fragments of free-radical initiators are almost always incorporated as end-

groups of the polymers whose polymerization they initiate.

Some submitters have found the question of whether initiators should be included in the description of a polymer to be troublesome. Should an initiator be included if its presence in the polymer was unintentional? EPA addressed this question in a March 19, 1981 reply to a letter from a company. In its letter of reply, EPA stated that:

. . . a free-radical initiator may or may not be intended to become chemically a part of the polymeric composition. For example it may become a substituent of the growing polymer. On the other hand, it may serve primarily to react with a chain-transfer agent, which then in turn starts the growth of each polymer chain. If [it] is a free-radical initiator intentionally added to become part of the polymeric composition, then it is subject to the two percent rule. . . .

In other words, EPA took the position that initiators are ordinarily intended to become part of the polymeric composition, by becoming substituents of the growing polymer, unless other special effects, such as the intervention of chain-transfer agents, prevent them from doing so.

EPA attempted further clarification of this question of "intent" in the Polymer Exemption Rule (40 CFR 723.250), which was published in the Federal Register of November 21, 1984 (49 FR 46066).

Section 723.250 defined "reactant" as ". . . a chemical substance that is used intentionally in the manufacture of a polymer to become chemically a part of the polymer composition." Expanding on this point in the discussion of the rule, EPA stated that reactants "include monomers, chain-transfer and cross-linking agents, monofunctional groups that act as modifiers, and other end groups that are not also monomers if they are incorporated into the polymer molecule." (49 FR 46069) Initiators, as the letter quoted above makes clear, fall into the category of "other end groups that are not also monomers."

Finally, in a letter to a company dated February 3, 1987, EPA stated that "intent" plays an important role in a company's determination of whether or not to include a free-radical initiator in the polymer description. While recognizing this, EPA reserved the right to raise questions relating to a reactant role for an initiator when it is charged at greater than two weight percent if there is obvious indication of significant incorporation of initiator into the polymer composition.

EPA believes that the record of its statements on polymer description supports its policy that free-radical initiators used at greater than two weight percent must be included in the

polymer descriptions. This is consistent with the Congressional mandate that EPA review new chemical substances under TSCA section 5. However, EPA recognizes that polymer manufacturers may have in good faith misinterpreted this policy. Therefore, EPA is issuing this policy statement to eliminate the confusion regarding the PMN requirements for polymers manufactured using free-radical initiators at greater than two weight percent. Further, EPA has decided to apply this policy only to polymers not listed on the Inventory as of the effective date of this document, rather than requiring alternative methods to correct the Inventory. This approach will reduce the reporting burden for polymer manufacturers and will not adversely affect the integrity of the Inventory.

II. Polymers That Are Considered To Be on the TSCA Inventory

The Inventory currently covers more than 65,000 chemical substances of which approximately 16,000 are identified as polymers. Very few of the polymers currently listed on the Inventory include the identity of a free-radical initiator in the polymer name. EPA does not know how many of the 16,000 polymers were actually manufactured using a free-radical initiator at greater than two weight percent at the time they were reported for the Inventory.

Further, persons who did not understand EPA's policy for treatment of free-radical initiators may have manufactured polymers on the Inventory, with the addition of a free-radical initiator not included in the Inventory description, without concluding that it would be a new chemical substance. Although EPA recognizes that some of these polymers might not be correctly represented on the Inventory, the Agency believes it is impractical to attempt to correct the existing Inventory entries by including the identity of each free-radical initiator in the name of a polymer which was actually manufactured using that initiator at greater than two weight percent. Therefore, the following policies are adopted as of the effective date of this document:

A polymer to be manufactured with one or more free-radical initiators, in which at least one initiator is used at greater than two weight percent, is considered to be included on the Inventory:

(1) *Category 1:* If the identical polymer description, without any initiator(s) is on the Inventory as of the effective date of this document. (Substances that are

considered to be on the Inventory include those that were reported for the original Inventory as well as those reported following PMN review via a Notice of Commencement of Manufacture or Import under 40 CFR 720.102 that was received by EPA on or before the effective date of this document.) or

(2) *Category 2*: If the identical polymer description, including the same initiator(s) in the name, is on the Inventory.

To help subsequent manufacturers of polymers with free-radical initiators who must comply with this policy determine whether a polymer falls in Category 1 or 2, EPA will flag those polymers that are on the Inventory as of the effective date of this document, which do not have free-radical initiators in the polymer name (i.e., Category 1).

Further, EPA recommends that persons submitting a bona fide Notice of Intent to Manufacture or Import for a polymer (under 40 CFR 710.7(g) or 720.25(b)) clearly indicate which monomers and other reactants will be used at greater than two weight percent, and those used at two weight percent or less, in order to expedite the Inventory search.

III. PMN Requirements for New Polymers

As of the effective date of this document, a polymer manufactured using greater than two weight percent of an initiator will be subject to the PMN requirements unless (1) it is on the Inventory under the policy criteria outlined in Unit II of this preamble, or (2) EPA agrees with the manufacturer's (or importer's) claim that an initiator used at greater than two weight percent is not a reactant incorporated into the polymer structure.

A free-radical initiator used in the manufacture of a polymer is considered incorporated into the polymer structure if it is known or can be reasonably ascertained that the use primarily involves chemical incorporation of one or more initiator fragments (other than a hydrogen atom) into the polymer. A manufacturer's claim that a free-radical initiator used to manufacture a polymer is not incorporated into the polymer structure, must be substantiated by adequate supporting information. EPA will not accept mere assertion by a manufacturer that a free-radical initiator is simply not incorporated. Information to support such an assertion could include, for example, a description of the activity of the initiator and the extent to which this activity will operate; an explanation of what is intended by this activity role; the extent

of incorporation of initiator-derived fragments; any measures taken to prevent or limit incorporation; any product properties or performance factors that would make incorporation undesirable; and any other technical, economic, or utility considerations that would sustain the manufacturer's claims.

If a polymer is manufactured using a free-radical initiator at two weight percent or less, the initiator does not have to be included in the Inventory description of the polymer. However, if at some future point, the manufacturer wants to increase the percentage of that free-radical initiator above two weight percent, this could require a PMN unless the polymer with the initiator is on the Inventory under the policy discussed above. Further, a manufacturer may request in a PMN for a new polymer that an initiator used at two weight percent or less be included in the Inventory description of the polymer by marking the appropriate "Identity" column in the polymer identification section on page 4 of the PMN form. This long-standing policy applies to any reactant used at two weight percent or less. If a manufacturer decides to include an initiator used at two weight percent or less as part of the Inventory name of a new polymer, the initiator may be used at levels greater than two weight percent, but may not be eliminated completely unless the polymer without the initiator is on the Inventory or if the manufacturer also submits a PMN for the polymer without the initiator. In such situations, it may be appropriate for a manufacturer to request permission from the section 5 Prenotice Coordinator (TS-794), U.S. Environmental Protection Agency, 401 M St. SW., Washington, DC 20460 or (202) 382-3745, to submit a consolidated PMN. (See discussion on consolidated notices in the preamble to the May 13, 1983 PMN final rule (48 FR 21734).

IV. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this document which clarifies a specific provision of the PMN rule is not "major" as that term is defined in section 1(b) because: The annual effect of the clarification of the rule on the economy will be less than \$100 million; it will not cause any significant increase in costs or prices for any sector of the economy or for any geographic region; and it will not result

in any significant adverse effects on competition, employment, investment, productivity, or innovation or on the ability of United States enterprises to compete with foreign enterprises in domestic or foreign markets. This document was submitted to the Office of Management and Budget (OMB) for review prior to publication.

B. Regulatory Flexibility Act

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA certifies that this document which clarifies a specific provision of the PMN rule will not have a significant economic impact on a substantial number of small businesses.

C. Paperwork Reduction Act

This document clarifies information collection requirements which have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. and have been assigned OMB control number 2070-0012.

List of Subjects in 40 CFR Parts 710 and 720

Chemicals, Environmental protection, Premanufacture notification, Reporting and recordkeeping requirements.

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Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Public Land Order 6371

[CO-930-09-4214-10; C-45714]

Cancellation of Public Land Order No. 6730; Withdrawal of National Forest System Land for Protection of Recreational Values; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order cancels Public Land Order No. 6730 and withdraws approximately 374 acres of National Forest System lands from mining for a period of 50 years for the protection of existing and planned recreational facilities near Aspen, Colorado. The lands have been and remain open to such other forms of disposition as may